2007 Annual Report of the West Virginia Pharmaceutical Cost Management Council

Authority to Act

> §5A-3C-8 (8) The Council shall report to the Legislature's joint committee on government and finance on or before the first day of September, two thousand four and on or before the thirty-first day of December, two thousand four and annually thereafter to the Legislature and provide recommendations to the Legislature on needed legislative action and other functions established by the article or requested by the joint committee on government and finance of the Legislature;

Executive Summary

This annual report details actions taken by the West Virginia Pharmaceutical Cost Management Council for calendar year 2007. The topics include the promulgation of advertising reporting rules, update on ongoing activities, evaluation of pending federal 340b legislation, consideration of the proposed regulation of pharmacy benefits managers, and review of federal and state requirements for tamper-resistant prescription pads.

The Council met seven times during calendar year 2007. Minutes of each meeting are attached in **Appendix A.**

Advertising Reporting Rule

Authority to Act

> §5A-3C-13 (b) The Council shall establish, by legislative rule, the reporting requirements of information by labelers and manufacturers which shall include all national aggregate expenses associated with advertising and direct promotion of prescription drugs through radio, television, magazines, newspapers, direct mail and telephone communications as they pertain to residents of this state.

On January 17, 2007, the Council voted to accept technical changes made to the advertising reporting rule by the Legislative Rulemaking Review Committee. On February 1, 2007, the Council held a special meeting to consider a technical error to the filed emergency rule and the regular legislative rule. Rather than being filed under the

West Virginia Pharmaceutical Cost Management Council, the rule was filed under the Pharmaceutical Advocate's Office which does not have rulemaking authority. This error aroused sufficient concern and the Council voted to withdraw both the emergency rule and the regular rule and refile both at a later date.

On April 17, 2007, the Council voted to refile the emergency rule and the regular rule as modified by the Legislative Rulemaking Review Committee with two changes: 1) the annual threshold for reporting payments to providers was lowered from $1,000 to $100 and the initial reporting period was set for July 1, 2007 to December 1, 2007 with the first reporting date of March 1, 2008.

On June 14, 2007, the Council learned that the Secretary of State's Office accepted the advertising reporting rule as an emergency rule. During that meeting, the Council reviewed the public comments received on the regular legislative rule. **(Public comments are attached at Appendix B)**

The Council accepted the comment from a consumers' coalition that rather than have the final reporting category for payments to providers be $10,000 and above, that it should be extended in $2,500 increments until all payments are reported.

The Council also accepted the comment from Bio and PhRMA that the reporting of payments to patient advocacy groups be limited to groups operating in West Virginia.

The emergency rule was withdrawn and refiled to reflect these modifications and the legislative rule was filed as a modified agency approved rule to reflect these changes. **(Appendix C)** The Secretary of State approved the amended emergency rule on August 22, 2007**.**

It is anticipated that the Legislative Rulemaking Review Committee will take up the advertising reporting rule during the January 2008 interim session.

Group Purchasing Arrangements

In 2006, the West Virginia Pharmaceutical Cost Management Council used its exemption from state purchasing statute and regulations to enter two group buying organizations on behalf of qualifying state and county agencies.

The Minnesota Multi-State Contracting Alliance for Pharmacy (MMCAP) is a voluntary purchasing consortium of 44 states and the City of Chicago. States become members and enroll MMCAP-eligible facilities. To enroll in MMCAP, facilities must be eligible to purchase from a state contract.

The two state psychiatric hospitals, the state acute care hospital, the state rehabilitation hospital, the state police, the state family planning program and thirty-four

local health departments enrolled in MMCAP during 2007. A financial analysis of the effectiveness of this group buying endeavor will be completed in early 2008.

The second group buying organization entered is the 340b Prime Vendor Program.

The Veteran's Healthcare Act of 1992 created a public health prescription drug pricing program called 340b. Through the 340b program, a variety of entities who receive federal funding can access this pricing program. Eligible entities include, but are not limited to, federally-qualified health centers (FQHCs), certain disproportionate share hospitals (DSH), hemophilia treatment centers (HTCs), AIDS drug assistance programs (ADAP) and family planning programs. 340b prices are a maximum of 51% below average wholesale prices (AWP) and approximately 18% below Canadian retail prices.

The federal Office of Pharmacy Affairs in the Department of Health and Human Services conducts a competitive and open bid process to contract with one vendor to purchase drugs on behalf of 340b eligible programs nationwide. The prime vendor program uses the collective purchasing power of the 340b entities to expand the number of pharmaceuticals available at sub-340b prices.

The West Virginia Family Planning Program in the Office of Maternal, Child and Family Health, Bureau for Public Health, Department of Health and Human Resources experience vast price changes in available contraceptives. As part of the program's search for more efficient and reliable ways of purchasing contraceptives, it asked the Pharmaceutical Cost Management Council to enter the 340b Prime Vendor Program. The Council and the Office of the Pharmaceutical Advocate worked closely with the Family Planning Program to fulfill all the documentation requirements for entry into the prime vendor program. The effectiveness of this arrangement will be evaluated in early 2008.

Central Fill Pharmacy

The Central Fill Pharmacy Board met throughout 2007. The Board completed documentation to become and independent nonprofit organization and developed a full budget. The Board devoted extensive time and effort which materially contributed to moving the Central Fill Pharmacy from a concept to a reality. It is expected that the capacity to deliver affordable and appropriate pharmaceutical products to thousands of uninsured and/or low-income West Virginians will emerge in early 2008.

Electronic Prescribing

Authority to Act

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annually thereafter to the Legislature and provide recommendations to the Legislature on needed legislative action and other functions established by the article or requested by the joint committee on government and finance of the Legislature;

In December 2007, as a result of its investigation of electronic prescribing, the Council recommended to the West Virginia Legislature that full consideration be given to legislation which would permit electronic prescribing. Governor Manchin introduced such a bill as part of his legislative package and the Legislature passed the bill. Governor Manchin signed Senate Bill 1001 into law on April 2, 2007.

The Pharmaceutical Advocate and the West Virginia Health Information Network worked closely with the new executive director of the Board of Pharmacy to develop the necessary legislative rules to allow electronic prescribing. At this writing, those rules are expected to be filed as emergency rules by the end of December 2007.

The 340b Program Improvement and Integrity Act of 2007 (S.1376/H.R.2606)

As outlined earlier in this report, Congress established the 340b Drug Pricing Program under the Veterans' Health Care Act of 1992 (Public Law 102-585). The program provides special drug pricing to safety net providers to maintain and enhance access to health care services.

The 340b Program Improvement and Integrity Act of 2007 (S.1376/H.R.2606) would extend 340b drug discounts to the inpatient settings of eligible hospitals (currently only drugs given in outpatient settings are eligible) and would extend 340b pricing to new categories of hospitals. Currently, nine hospitals in West Virginia participate in the 340b program. The pending federal legislation would make thirty-three hospitals eligible. The West Virginia Hospital Association prepared a list of eligible hospitals and an estimate of savings for each hospital. **(The list of hospitals and estimated savings is attached at Appendix D)**

Charleston Area Medical Center (CAMC) presented an outline of the pending legislation and how it would affect CAMC and other hospitals. CAMC requested that the Council endorse the legislation.

PhRMA commented that greater oversight of the 340b program is needed; but the official position of the association on the pending legislation is neutral.

At the October 16, 2007 meeting, the Council voted by consensus to endorse the legislation and send correspondence to members of the West Virginia congressional delegation requesting they co-sponsor bills in their respective houses. **(Appendix E)** At the writing of this report, Congressman Nick Jo Rahall responded in the affirmative. **(Appendix F)**.

Pharmacy Benefit Manager (PBM) Regulation

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Pharmacy Benefit Managers (PBMs) serve as large brokers for insurance providers. PBMs may offer a wide variety of services, but most commonly negotiate rebate arrangements with manufacturers, establish and manage formularies, establish payment rates for participating pharmacies and process and analyze prescription drug claims. As such PBMs use their collective buying power to obtain low drug prices; however, anecdotal litigation between commercial insurers and PBMs raise concerns that PBMs may keep excessive profits through non-transparent contract arrangements and may act in ways that are not in the best interests of their customers, or commercial insurance companies.

During the last regular session of the West Virginia Legislature it considered the H.B. 4656, the Pharmacy Benefit Manager Licensing and Regulation Act. This act seeks to establish standards and criteria for the licensing and regulation of Pharmacy Benefit Managers and includes the filing of "copies of all contracts with insurers, pharmaceutical manufacturers or other persons utilizing the services of the Pharmacy Benefit Manager for pharmacy benefit management services."

At its October 16, 2007 meeting, Terry Latanich, Consultant, Pharmaceutical Care Management Association presented to the Council on the proposed PBM regulation proposal.

Mr. Lantanich reported that: 1) more than 210 million Americans receive pharmacy benefits through PBMs; 2) PBMs estimated to manage $204 billion in drug expenditures in 2008 and 3) PBMs estimated to reduce prescription drug costs by 20 percent compared to retail purchases with no pharmacy benefit manager.

Mr. Latanich said that in 2007 alone, 19 states have considered and rejected legislation that would impose restrictions on PBMs.

Randi Reichel, a consultant with America's Health Insurance Plans also presented to the Council at the October meeting. Ms. Reichel said state regulation would be an unnecessary intrusion into health insurers' negotiations with the PBMs. She stated that insurers did not believe the industry needed this kind of assistance. Further, if PBMs were required to file contracts negotiated with insurers with a governmental agency, it may adversely impact the prescription drug coverage insurers could offer to their subscribers.

Tim Murphy, Attorney Supervisor with the WV Insurance Commission. Mr. Murphy informed the Council that PBMs sometimes voluntarily register as third party administrators (TPAs) with the Commission. This enables the Commission to investigate complaints against PBMs and the Commission can use both administrative and civil monetary penalties against PBMs if the investigation reveals misconduct.

Over the next two months, the Council with the Insurance Commission, contacted the two states which enacted PBM regulation requiring PBMs to file contracts with a government entity - the State of South Dakota and the State of Maine. Neither state could offer data or testimony on the effect of the legislation - positive or negative - on the availability and/or affordability of prescription drug coverage. The National Association of Insurance Commissioners was also requested to share any data or analysis of these statutes; such information is not available.

At its December meeting, the Council elected to continue to seek analysis of the effects of PBM transparency regulation before making any recommendation to the legislature.

Tamper-resistant prescription drug pads

At its December 18, 2007 meeting, the Council investigated the possible effects of the federal requirement that all Medicaid prescriptions be written on tamper-resistant drug pads effective April 1, 2008.

Peggy King, Pharmacy Director for Medicaid reviewed the federal requirement and the federal standards for tamper-resistant pads. The tamper-resistant requirements apply to handwrite prescriptions, not those emailed, faxed or phoned in. **(Appendix G).**

John Harden of Standard Register, a vendor which serves states which have a statewide requirement that all controlled substances be written on tamper-resistant pads presented the following data:

1. Based on 2005 data the Kaiser Family Foundation estimates that West Virginia Medicaid program experiences between $3.4 and $11.28 million annually in prescription drug fraud;
2. A 2007 SAMSHA report lists West Virginia as having the 7th highest rate of abuse of prescription drug pain relievers by teens at 8.9% (http://www.mediacampaign.org/teens/brochure.pdf);
3. Working on the data from the New York experience, West Virginia could be expected to save $25,937,778 statewide per year if it adopted tamper-resistant drug pads for controlled substances.

The West Virginia Pharmacists Association and the West Virginia State Medical Association both shared concerns with complying with the new federal statute. More information will be gathered and the Council will explore this issue further at its first meeting in 2008. (**Appendix G - Tamper-resistant prescription pad presentations**).

Conclusion

During calendar year 2007, the Council redoubled its efforts to fulfill the statutory requirement to promulgate an advertising and reporting rule. The Secretary of State and her staff provided invaluable assistance in this process. As in 2006, legislative staff also lent guidance in regard to the legislative rulemaking process. The Council appreciates the assistance of these professionals.

In 2008, the Council will:

- assess the effectiveness of the group-buying agreements it entered on behalf of the state;

- examine how it can use its purchasing exemption to assist other state agencies, how to make available the 340b and other low-cost drug programs to a greater number of West Virginians;

- redouble its efforts to communicate with other states to explore new and innovative ways to lower drug costs;

- interact more closely with consumers around the state to assess pharmaceutical issues; and

- work to further fulfill the remaining provisions of its statutory mandate.

Appendices

Appendix A	Minutes of all Council meetings for calendar year 2007
Appendix B	Public Comments in response to the Proposed Advertising Reporting Rule
Appendix C	Amended Emergency Advertising Reporting Rule and Amended Agency Approved Rule
Appendix D	West Virginia Hospital Association estimates of individual hospital savings from The 340b Program Improvement and Integrity Act of 2007 (S.1376/H.R.3606)
Appendix E	Letter to Congressional Delegation requesting co-sponsorship of (S.1376/H.R.3606)
Appendix F	Letter from Congressman Rahall announcing his co-sponsorship of H.R. 3606
Appendix G	Tamper-resistant prescription pad presentations